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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,703	07/20/2001	Bruce J. Barclay	VASC 1020-2	2083

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/910,703	BARCLAY ET AL.
	Examiner	Art Unit
	Brian E Pellegrino	3738

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,8,9,11,19-23,25,26,38-42,74-78,101-104 and 108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,8,9,11,19-23,25,26,38-42,74-78,101-104 and 108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/26/04 has been entered.

Claim Objections

Claim 108 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim depends from a canceled claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,4,8,9,23,25,26,38-41,74-77,108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herzog et al. (WO 98/08482) in view Kropf (4760849). Herzog et al. disclose a prosthesis in the form of a stent, a sleeve having an interior

surface that houses the stent, and a NO generator within the sleeve interior, page 6, lines 7,8, page 14, lines 20-32. Herzog also discloses a method of delivering the agent (NO generator) to the target site is an anti-proliferative or anti-restenotic agent, since it inhibits restenosis, page 9, lines 16-23. The stent can be made of metal, page 11, line 22. Herzog also discloses biodegradable polymers can be used to control rates of delivery of NO, page 12, lines 20,21. Herzog additionally discloses the sleeve material on the stent is porous, and substantially impervious to blood, page 12,lines 2-5. The agent can also be encapsulated, page 12, line 11. Herzog et al. also disclose that a delay-release material is used to control the release of the agent into the blood vessel, page 11, lines 26,27. However, Herzog et al. fail to disclose a coiled stent with radial openings and side members connecting longitudinal members. Kropf teaches a coiled stent, Fig. 5. Kropf teaches that the structural design enables the prosthesis to be deployed in a small profile reducing the likelihood of vessel trauma, col. 3, lines 8-13. It would have been obvious to one of ordinary skill in the art to substitute the stent design of Kropf in the device of Herzog et al. in order to provide a stent with good flexibility and a small profile for delivery.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herzog et al. (WO 98/08482) in view Kropf '849 as applied to claim 38 above, and further in view of McNamara et al. (5147370). Herzog as modified by Kropf is explained supra. However, Herzog in view of Kropf do not disclose the prosthesis comprising turns touching one another when in the expanded state. McNamara et al. show a coil (Fig. 1) with turns touching one another when in the expanded state, see also col. 3, lines

55,56. McNamara also teaches the coil is to be designed with closely spaced turns, col. 6, lines 19-23. It would have been obvious to one of ordinary skill in the art to use a closely spaced turned coil as taught by McNamara with the coiled body of Herzog as modified by Kropf in order to provide more structural support to the vessel.

Claims 19-22,42,78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herzog et al. (WO 98/08482) in view Kropf '849 as applied to claims 38 and 74 respectively above, and further in view Ragheb et al. (5873904). Herzog as modified by Kropf is explained supra. However, Herzog in view of Kropf do not disclose the polymer sleeve made from PTFE and the use of multiple agents. Ragheb teaches that porous polymers, such as PTFE can be placed on the stent (col. 5, lines 43,44,50) and is used for controlling drug release, col. 6, lines 56-60. It would have been obvious to one of ordinary skill in the art to substitute PTFE as taught by Ragheb for the polymer sleeve material of Herzog as modified by Kropf in order to control release rates of therapeutic material administered to the patient. Ragheb also teaches the use of first and second dispensable agents, col. 5, lines 58,59,63 and col. 6, lines 3-14. It would have been obvious to one of ordinary skill in the art to use a second agent as taught by Ragheb with the stent of Herzog as modified by Kropf such that the device has enhanced capabilities and multiple treatment capabilities. Regarding claim 22, it would have been an obvious matter of design choice to modify the ability of the stent to release at least half of a first agent before a second is released, since applicant has not disclosed that using any set amount of one over another provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art,

furthermore, would have expected Applicant's invention to perform equally well with the rates and amounts taught by Ragheb or the claimed at least half of first agent in claim(s) 22 because both designs perform the same function of releasing agents into the patient.

Claims 101-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herzog et al. (WO 98/08482) in view Kropf '849 as applied to claims 38 and 74 respectively above, and further in view of Hanson (5399352). Herzog as modified by Kropf is explained supra. However, Herzog in view of Kropf do not disclose the sleeve interior has open spaces. Herzog does disclose an interior region with the NO generator in a polymer and a second sleeve or layer is placed thereon. Hanson teaches that a reservoir or open space is used alone to hold drugs, such as NO generators to prevent restenosis in combination with a prosthetic device, col. 5, lines 60-62, col. 6, lines 3-5. Hanson also shows (Fig. 4) the reservoir is an open space **20** for the drug. It would have been obvious to one of ordinary skill in the art to use a reservoir or open spaces as taught by Hanson within the sleeve interior of the stent of Herzog as modified by Kropf so that a sufficient amount of drug can be administered to the site. The modification of eliminating the inner polymer material that holds the drug creates more space and can be made into a reservoir area, such that a greater amount of agent can be delivered.

Respons to Arguments

Applicant's arguments with respect to claims 38,74 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738

Brian E. Pellegrino